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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,406	03/17/2004	Thomas Weisel	MIT1.PAU.02	5563
23386	7590	05/12/2010	EXAMINER	
Myers Andras Sherman LLP 19900 MacArthur Blvd. Suite 1150 Irvine, CA 92612			NGUYEN, TUAN VAN	
			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/803,406	Applicant(s) WEISEL ET AL.	
	Examiner TUAN V. NGUYEN	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7 and 28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1 and 28 are pending and they are presented for examination.
2. This Office action is in response to the RCE filed on February 01, 2010.

Continued Examination Under 37 CFR 1.114

3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after the final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 01, 2010 has been entered.

Allowable Subject Matter

4. Further consideration of Toy et al. (U.S. 5,618,290) and Trott (U.S. 5,312,422) references, the indicated allowability of claims 7 and 28 is withdrawn in view of new ground of rejection. The rejection is set forth in detail below.

Specification

5. The abstract of the disclosure is objected to because the abstract exceed 150 words in length. Correction is required. See MPEP § 608.01(b).

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6. The disclosure is objected to because of the following informalities: reference numbers 56 and 58 in Fig. 15 are not described in the specification. Appropriate correction is required.

Drawings

7. The drawings are objected to under 37 CFR 1.83(a) because they fail to show slot 28c in Fig. 15 (see [0072]), needle assembly 20b in Fig. 13 (see [0069]), gathering arm 38b in Fig. 14 (see [0070]), needle assembly 20c in Fig. 15 (see [0071]), and vertical slot 60 in any of Figs. 16, 16A-16B (see [0074]) as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d).
Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top

margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. **Claims 7 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Toy et al. (US 5,618,290) in view of Trott (U.S. 5,312,422).**

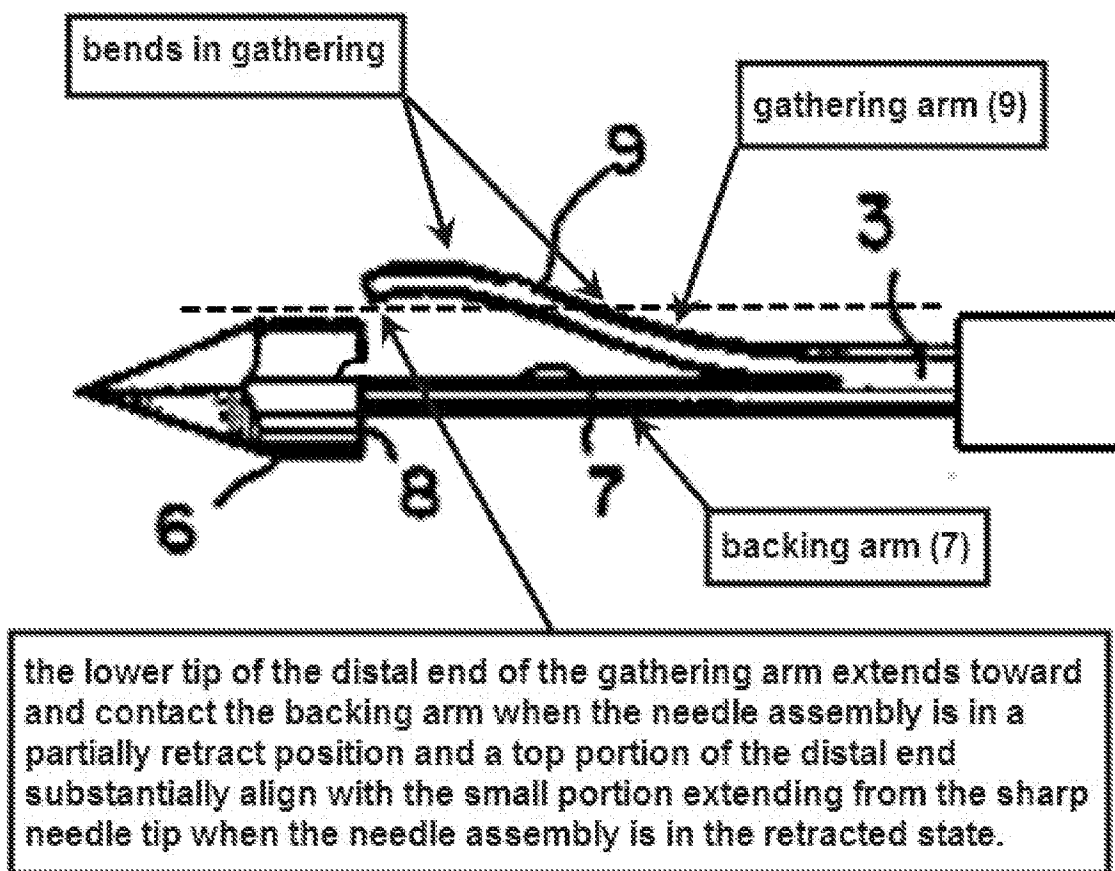
11. Regarding claim 28, Toy discloses a suturing device (1) having a proximal end and a distal end, the device being operable to move a suture through body tissue,

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comprising: a sheath (11) or **an elongate shaft** having a hollow configuration; **a handle assembly** (17s) coupled to the shaft; a needle shaft (3) or **an actuating rod** having a proximal end and a distal end, the actuating rod being disposed to extend between the handle assembly and the shaft; **a needle assembly** (6, 7, 8, and 9) disposed at the distal end of the actuating rod and movable back and forth with the actuating rod between an extended state relative to the elongate shaft (Fig. 4) and a retracted state (Fig. 3) relative to the elongate shaft; **bifurcated portions** of the needle assembly defining **a suture slot** (located between reference numbers 7 and 9 as shown in Fig. 4, Col. 3:64-66 and Col. 4: 40-51) with a proximal end and a distal end, the bifurcated portions including **a backing arm** (7) and **a gathering arm** (9) that are integral with one another at the proximal end of the suture slot, the backing arm and gathering arm having a proximate but spaced relationship when the needle assembly is in the retracted state (in Col. 4: 40-51, Trot discloses the latch (9) or gathering arm is created by an L-shape cut (7), the latch is then shaped by bending to provide an enlarged latch opening, and the inner diameter of sheath (11) is slightly larger than the outer diameter of shaft (3). Examiner contends that the small clearance between the inner diameter of sheath (11) and shaft (3) will allow the gathering arm (9) to extending outward away from the backing arm (7) when the needle assembly is in retracted position, thereby forming a suture lot) and having a separated and further spaced relationship when the needle assembly is in the extended state, the backing arm and gathering arm being biased to the separated relationship (Fig. 4 and Col. 3: 67

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to Col. 4: 5); **a sharp needle tip** (Fig. 4, near reference no. 6) formed at a distal end of the backing arm; and gathering arm includes **a distal end and bends** (see annotated figure) causing the distal end of the gathering arm to extend away from the backing arm to define a wide passage into the suture slot when the needle assembly is in the extended state and the backing arm and gathering arm have the separated relationship and the distal end of the gathering arm aligning with the proximally extending portion at a position that is closer to the distal end of the suture slot than the proximal end of the suture slot (see annotated figure)(Col. 3: 20 to Col. 4: 25).



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12. The annotated figure above also show the lower tip of the distal end of the gathering arm (9) extends toward and contact the backing arm (7)(which is represented by hidden line) when the needle assembly is in a partial retract position.
13. Toy discloses the invention substantially as claimed except for disclosing (1) the needle assembly being biased to the retracted state and (2) a small portion extending proximally from the sharp needle tip to form a hook around an opening at a distal end of the suture slot to retain the suture, a portion of the opening remaining distally of the elongate shaft when the needle assembly is in the retracted state. However, Trott discloses a suturing needle assembly (Figs. 1 and 3-4) includes a positive locking mechanism (Figs. 8 and 9) to bias the needle assembly in a retracted state during insertion and removing the suturing needle assembly to prevent the suture from disengaging the needle (Col. 4: 39-50). It would have been obvious to one of ordinary skill in the art to incorporate the teaching of Trott into the suturing needle assembly as disclosed by Toy so that it too would have the same advantage. Trott further discloses a hook (46) is positioned near the needle tip 38 (Fig. 3-4). Apparently, the advantage of the hook is preventing the suture inadvertently disengaging the needle before the needle is retracted into the locked position. It would have been obvious to incorporate the hook as disclosed by Trott into the hook (8) as disclosed by Toy (Fig. 4 and Col. 3: 24-27) so that it too would have the same advantage.

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14. With respect to the limitation of “causing the distal end of the gathering arm to substantially align with the small portion extending from the sharp needle tip when the needle assembly is in the retracted state”, as modified by Trott, the device of as shown in Figure 4 of Toy’s drawings, which is reproduced and annotated in page 6 above, shows a portion of the distal end of the gathering arm substantially align with the hook or small portion extending from the sharp needle tip when the needle assembly is in the retracted state.
15. Regarding claim 7, Toy discloses the bifurcated portions of the needle assembly have an outer surface in the shape of a cylinder (Col. 4: 35-38).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TUAN V. NGUYEN whose telephone number is (571)272-5962. The examiner can normally be reached on 9:00 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, AnhTuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/TUAN V NGUYEN/
Examiner, Art Unit 3731